

When Does “Invention” Happen? Inventorship and Conception of an Invention

By: John J. Cunniff, Esq.

The case *University of Pittsburgh v. Hedrick* (2008-1468, Fed. Cir. [July 23, 2009]) involved two teams of researchers, one from the University of Pittsburgh and the other from UCLA, that both claimed inventorship of certain stem cells. Stem cells are cells that are undifferentiated; that is, they have the ability to become different types of cells, such as bone, cartilage, fat, or muscle cells. When cells differentiate during development, they gain the properties of certain specific types of cells and lose the ability to become other types of cells. It is important to note that the quality of being a “blank slate” is what makes stem cells valuable in biotech research. In this case, the related research involved making fat cells revert to an earlier stage of development and essentially become stem cells.

In 1996, University of Pittsburgh (Pitt) researchers Adam Katz and Ramon Lull began investigating the isolation of cells obtained from liposuctioned adipose (fat) tissue. They determined that under certain conditions, isolated adipose cells could “de-differentiate” into more primitive cells and then “re-differentiate” into adipocytes (fat cells). In February 1997, they published a paper indicating that these de-differentiated cells could also be caused to become other types of cells, such as bone, cartilage, and muscle cells.

In April 1997, a group of researchers from a third lab published a paper describing stem cells derived from bone marrow. Dr. Katz saw similarities between the cells derived from bone marrow and his own adipose-derived cells, including their ability to be grown and cultured for extended time. The Pittsburgh team had also observed and documented cells changing into what appeared to be a nerve cell, which was noted in a lab notebook with the remark, “Let’s do further studies...to substantiate....”

In July 1997, Marc Hedrick, one of the researchers from UCLA, joined the Pitt lab for a one-year fellowship. Upon the completion of the fellowship, he returned to UCLA where he continued his previous research in a new lab of his own. This research included demonstrating that the adipose derived stem cells were not the same as the previously described bone marrow-derived stem cells.

Ultimately, the dispute on inventorship centered on when the stem cells derived from the adipose cells were “conceived.” Hedrick maintained that conception of the invention did not occur until the cells were shown to be different from the previously described bone-marrow derived stem cells. This was accomplished by Hedrick and his fellow UCLA researchers after he left Pitt, and therefore, he and his fellow UCLA researchers claimed that they were the inventors of these stem cells. Pitt however, maintained that conception of the invention occurred when the stem cells were isolated (before Hedrick arrived at lab) and that Hedrick only contributed to reduction to practice of the invention by verifying what the Pitt researchers already surmised.

The language of the claims was considered in determining when conception occurred. Claim 1 recited, “An isolated adipose-derived stem cell that can differentiate into two or more of the group consisting of a bone cell, a cartilage cell, a nerve cell, or a muscle cell.” Even though the specification of the patent described the stem cells as being different from bone marrow-derived stem cells, the Court of Appeals for the Federal Circuit (CAFC) did not consider it necessary to refer to the specification to interpret the claims. The CAFC also did not consider an amendment which inserted the phrase “adipose-derived” to have been a disavowal of claim scope.

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The CAFC held that the trial court was correct in determining that conception occurred before Hedrick arrived at Pitt. They held that conception requires that inventor have “an idea that was definite and permanent enough that one skilled in the art could understand the invention...” They rejected Hedrick’s contention that the Pitt researchers did not know that the invention contained every limitation of the claims. Instead, they held that the inventor must “show that he had the complete mental picture and could describe it with particularity; the discovery that the invention actually works is part of its reduction to practice.” Absolute certainty was not required and confirmation that cells were not the same as bone marrow-derived cells was reduction to practice, not conception. The CAFC stated, “Knowledge in the context of a possessed, isolated biological construct does not mean proof to a scientific certainty that the construct is exactly what a scientist believes it is. Conception requires a definite and permanent idea of the operative invention...”

While this case focused in large part on claim language and on statements made during prosecution of the application, underlying the entire case was the researchers’ ability to rely on documented dates along the process of invention. While the case was not won or lost on the contents of laboratory notebooks, an absence of such records, or incomplete records, could have resulted in a very different holding. Not only are complete records necessary in determining a date of invention when there is a question of the date of conception between competing research groups, they can be equally critical when determining inventorship within a single research group or between collaborating groups.

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John is an associate in the Akron office of Hahn Loeser & Parks LLP. He focuses his practice in intellectual property and technology; and patent, trademark, and copyright law. John is admitted to practice law in Ohio, before the U.S. District Court for the Northern District of Ohio and District Court of Colorado; the Sixth Circuit Court of Appeals; and the U.S. Patent and Trademark Office.